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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,417	05/22/2006	Miki Kobayashi	Q94782	1747

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EXAMINER	
KIM, JENNIFER M	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
10/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,417	KOBAYASHI ET AL.	
	Examiner	Art Unit	
	JENNIFER M. KIM	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/22/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 8-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 8-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/22/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3, 8 and 9-11 are presented for Examination.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-3 and 8-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the "treatment of chronic pelvic pain syndrome", does not reasonably provide enablement for the "prevention of chronic pelvic pain syndrome". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

3. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, and predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors**

have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: All of the rejected claims are drawn to a composition and a method for **preventing** or treating chronic pelvic pain syndrome, which comprises a phosphodiesterase 1 (PDE 4) inhibitor, or a pharmaceutically acceptable salt thereof, as an active ingredient. The nature of the invention is extremely complex in that it encompasses the actual **prevention** of a chronic pelvic pain syndrome such that the subject treated with above compounds does not contract a chronic pelvic pain syndrome.

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass **prevention** of a chronic pelvic pain syndrome in humans which has potentially many different causes (i.e. many different mutations or combination of mutations). Each of which may or may not be addressed by the administration of the claimed compounds.

Guidance of the Specification: The guidance given by the specification as to how one would administer the claimed compounds to a subject in order to actually **prevent** a chronic pelvic pain syndrome is minimal. All of the guidance provided by the specification is directed towards treatment rather than **prevention** of a chronic pelvic pain syndrome.

Working Examples: All of the working examples provided by the specification are directed toward the treatment rather than prevention of a chronic pelvic pain syndrome.

State of the Art: While the state of the art is relatively high with regard to treatment of a chronic pelvic pain syndrome, the state of the art with regard to prevention of such disorders is underdeveloped. In particular, there do not appear to be any examples or teachings in the prior art wherein a compound similar to the claimed compounds was administered to a subject to **prevent** development of a chronic pelvic pain syndrome. The state of the art, McMichael (U.S. Patent No. 7,101,847 B2) teaches that non-inflammatory chronic pelvic pain is **extremely difficult** to treat because its cause is unknown. The primary goal of treatment is to relieve symptoms. (column 2, lines 43-47). The state of the art, Mak et al. (U.S.Patent No. 6,987,129 B2) teach that there is **no cure** for **interstitial cystitis** at this time. (column 11, lines 53-54). To the extent that the instant claims are drawn to "prevention", which is highly speculative, a greater amount of evidence is required to show its operability in humans.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual **prevention** of a chronic pelvic pain syndrome in a human subject with the claimed compounds makes practicing the claimed invention unpredictable in terms of **prevention** of a chronic pelvic pain syndrome.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed compounds and test the combination in the model system to determine whether or not the combination is effective for **prevention** of a chronic pelvic pain syndrome. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regard prevention of a chronic pelvic pain syndrome with any compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification of prior art regarding prevention of a chronic pelvic pain syndrome with any compound, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to prevent the development of a chronic pelvic pain syndrome in a subject by administration of one of the claimed compounds.

Therefore, a composition and a method of **preventing** in a subject a chronic pelvic pain syndrome administering PDE 4 inhibitor is not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Mak et al. (U.S.Patent No. 6,987,129 B2).

Mak et al. teach that roflumilast, ariflo (SB207499) are well known phosphodiesterase type IV (PDE IV) inhibitors with a pharmaceutically acceptable carrier. (column 15, lines 40-50, column 20, line 30).

Applicants' recitation of the intended use of preventing or treating chronic pelvic pain syndrome of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. In this case, Mak et al's teaching clearly anticipate the claimed invention because Mak et al. teaches the same composition constitutes with the same active agent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mak et al. (U.S.Patent No. 6,987,129 B2).

Mak et al. teach methods for treating a variety of disorders such as **interstitial cystitis** using a variety of compounds including phosphodiesterase inhibitors. (abstract, column 4, lines 46-50, column 11, lines 37-67). Mak teaches that the phosphodiesterase inhibitor includes roflumilast and ariflo (SB207499) which is phosphodiesterase IV inhibitors.

Mak et al. do not illustrate the actual treatment of interstitial cystitis with the phosphodiesterase IV inhibitors such as roflumilast and ariflo (SB207499).

It would have been obvious to one of ordinary skill in the art to employ phosphodiesterase IV inhibitors such as roflumilast and ariflo (SB207499) for an actual treatment of interstitial cystitis because Mak et al. teach that the instantly claimed compounds such as roflumilast and ariflo (SB207499) are disclosed by Mak et al. for the treatment of interstitial cyclists. It would have been obvious to one of ordinary skill in the art to employ any one of the agents including phosphodiesterase IV inhibitors such as roflumilast and ariflo (SB207499) when specific agents such as roflumilast and ariflo (SB207499) are taught as equally effective in the treatment of interstitial cystitis and such utility would be retained. There is a reasonable expectation of successfully treating interstitial cystitis with phosphodiesterase IV inhibitors including roflumilast and ariflo (SB207499) because Mak et al. clearly teach and suggest the employment of

phosphodiesterase IV inhibitors including roflumilast and ariflo (SB207499) for the treatment of interstitial cystitis.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1617

Jmk
September 26, 2008